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APR 4 2006

510(k) SUMMARY
as required per 807.92(c)

Submitter's Name and Address: Draeger Medical Systems, Inc.
16 Electionics Avenue
Danvers, MA 01923

Contact Person: Karen Iorio
Director QA/RA
Ph: (978) 564-8364
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Date submission was prepared: January 25, 2006

Device Name:
Common Name: System, Network and Communication, Physiological Monitors

Classification Name: MSX

Regulation Number: 21 CFR 870.2300

Class: 2

Legally Marketed Device Identification: Infinity Explorer

Device Description:

The Infinity Explorer is a software-driven application that allows the user to extend the viewing capability of the Infinity modular monitors and integrate additional patient information on a single display. Infinity Explorer is capable of displaying real-time patient data, providing control back to the bedside and integrating other applications with patient data on the PC. This Special submission includes minor modifications to the hardware and software.

Testing has been performed to verify the overall performance of the INFINITY Explorer with VF6 modifications and the new MDS III.

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Intended Use:

The Infinity Explorer is a critical care workstation intended to display physiological parameters received from Infinity Modular Monitors and to visually display alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

Substantial Equivalence:

Assessment of non-clinical performance data for equivalence:

Verification and validation testing performed indicate that the modifications implemented are as safe and effective as previous versions and have not altered the fundamental technology of the device(s).

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability:

Not applicable

Sterilization:

Not applicable

Standards and Guidance: IEC 60601-1-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Draeger Medical Systems, Inc.
c/o Mr. Thomas M. McIntosh
Regulatory Affairs Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K060254
Trade Name: Infinity Explorer
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: March 17, 2006
Received: March 20, 2006

Dear Mr. McIntosh:

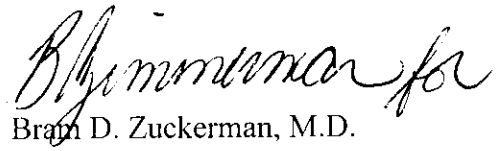
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060254

510(k) Number (if known):_____

Device Name: Infinity Explorer

Indications for Use

This device is capable of displaying physiological parameters received from Infinity Modular monitors and visually displaying alarm data for those parameters. The device is capable of displaying DICOM images received over a hospital information system.

The device is intended to be used in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The device is intended for use with the adult, pediatric and neonatal populations.

MRI Compatibility Statement:
Infinity Explorer is not compatible for use in a MRI magnetic field.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060254